

Message

From: Shams, Dahnish [Shams.Dahnish@epa.gov]
Sent: 11/30/2021 1:33:34 PM
To: Morozov, Viktor [Morozov.Viktor@epa.gov]
Subject: FW: Peer Review of PBPK Modeling for Chloroprene Follow Up: Revised Draft Report
Attachments: Revised Draft Chloroprene PBPK Follow-on Report 11.17.21.docx

FYI – here was the report Paul looked at.

Chemical & Pollutant Assessment Division (CPAD)
Center for Public Health and Environmental Assessment (CPHEA)
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From: Shams, Dahnish
Sent: Wednesday, November 17, 2021 11:06 AM
To: Schlosser, Paul <Schlosser.Paul@epa.gov>; Kapraun, Dustin <Kapraun.Dustin@epa.gov>
Cc: White, Paul <White.Paul@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>; Morozov, Viktor <Morozov.Viktor@epa.gov>
Subject: FW: Peer Review of PBPK Modeling for Chloroprene Follow Up: Revised Draft Report

Paul/Dustin – Can one of you take a quick scroll through the comments for any red flags? This is the final step of the peer review. Assuming no red flags, I will accept this as the final report and close out the peer review.

- Dahnish

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From: Cowen, Tracey [USA - EMP] <TCowen@versar.com>
Sent: Wednesday, November 17, 2021 11:02 AM
To: Shams, Dahnish <Shams.Dahnish@epa.gov>
Cc: Husain, Hassan [USA - EMP] <hhusain@versar.com>
Subject: Peer Review of PBPK Modeling for Chloroprene Follow Up: Revised Draft Report

Hi Dahnish,

Please see attached the revised comment report. We contacted the reviewers to request that they review their written comments to confirm and where appropriate clarify their tiering. Drs. Hsieh and Portier have provided additional edits/tiering of their comments and these revisions have been incorporated into the draft report. Drs. Shao, Yang, and Zhu checked their comments and confirmed that they had no additional edits. Dr. Smith is currently unavailable. We have contacted his assistant but received no response to our inquiry.

Let us know if you have any questions or comments.

Thanks,
Tracey

Tracey L. Cowen

Environmental Scientist
Environmental Services Group



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From: Husain, Hassan [USA - EMP] <hhusain@versar.com>
Sent: Wednesday, November 10, 2021 3:19 PM
To: Cowen, Tracey [USA - EMP] <TCowen@versar.com>
Subject: FW: In-Vitro Update for Peer Review of PBPK Modeling for Chloroprene

Can you reach out to the reviewers for a final confirmation on Dahnish's comment below?
"The EPA team has no comments, but however, do you mind asking the reviewers to take one more quick pass of their written comments to confirm and where appropriate clarify their tiering (e.g., Tier 1, Tier 2, Tier 3)? "

Hassan Husain
Senior Program Manager
Environmental Services Group



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From: Shams, Dahnish <Shams.Dahnish@epa.gov>
Sent: Wednesday, November 10, 2021 3:04 PM
To: Husain, Hassan [USA - EMP] <hhusain@versar.com>
Subject: RE: In-Vitro Update for Peer Review of PBPK Modeling for Chloroprene

Hi Hassan – I just wanted to check on the chloroprene report. Any chance we can get the final report by the end of next week?

- Dahnish

Chemical & Pollutant Assessment Division (CPAD)
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From: Shams, Dahnish
Sent: Tuesday, November 2, 2021 4:09 PM
To: Husain, Hassan [USA - EMP] <hhusain@versar.com>
Subject: RE: In-Vitro Update for Peer Review of PBPK Modeling for Chloroprene

Hassan – The EPA team has no comments, but however, do you mind asking the reviewers to take one more quick pass of their written comments to confirm and where appropriate clarify their tiering (e.g., Tier 1, Tier 2, Tier 3)?

- Dahnish

Chemical & Pollutant Assessment Division (CPAD)
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From: Husain, Hassan [USA - EMP] <hhusain@versar.com>
Sent: Tuesday, October 26, 2021 8:22 PM
To: Shams, Dahnish <Shams.Dahnish@epa.gov>
Subject: RE: In-Vitro Update for Peer Review of PBPK Modeling for Chloroprene

Dahnish,
Attached is the updated draft report and comment matrix. Let us know if you have any questions or comments as we get closer to the final report.

Hassan Husain
Senior Program Manager
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From: Shams, Dahnish <Shams.Dahnish@epa.gov>
Sent: Tuesday, October 26, 2021 2:08 PM
To: Husain, Hassan [USA - EMP] <hhusain@versar.com>
Subject: RE: In-Vitro Update for Peer Review of PBPK Modeling for Chloroprene

Ok thanks Hassan! Appreciate the quick response.

- Dahnish

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From: Husain, Hassan [USA - EMP] <hhusain@versar.com>
Sent: Tuesday, October 26, 2021 1:59 PM
To: Shams, Dahnish <Shams.Dahnish@epa.gov>
Subject: RE: In-Vitro Update for Peer Review of PBPK Modeling for Chloroprene

Dahnish,
We got Dr. Smith's comments yesterday afternoon. We have incorporated the comments and are finalizing the report and matrix to send over to you. Should be there later today.

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Senior Program Manager
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From: Shams, Dahnish <Shams.Dahnish@epa.gov>
Sent: Tuesday, October 26, 2021 1:54 PM
To: Husain, Hassan [USA - EMP] <hhusain@versar.com>
Subject: RE: In-Vitro Update for Peer Review of PBPK Modeling for Chloroprene

Hassan – Hope all is well. Quick question: do you have any updates on the final reviewers comments (Dr. Smith?)?

- Dahnish

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From: Husain, Hassan [USA - EMP] <hhusain@versar.com>
Sent: Thursday, September 30, 2021 11:58 AM
To: Shams, Dahnish <Shams.Dahnish@epa.gov>
Subject: RE: In-Vitro Update for Peer Review of PBPK Modeling for Chloroprene

Dahnish,

Are you looking for reviewer attribution? There is a specific section at the back end that has each reviewers comments organized together, we could certainly put this in a table if that helps. Give me a call when you get a chance, happy to discuss further.

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From: Shams, Dahnish <Shams.Dahnish@epa.gov>
Sent: Wednesday, September 29, 2021 2:40 PM
To: Husain, Hassan [USA - EMP] <hhusain@versar.com>
Subject: RE: In-Vitro Update for Peer Review of PBPK Modeling for Chloroprene

Hassan – Quick question: Is it possible to create a table at the front of the document that indicates which reviewers responded to each question? This would help us to review the document?

- Dahnish

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From: Husain, Hassan [USA - EMP] <hhusain@versar.com>
Sent: Tuesday, September 21, 2021 9:03 PM
To: Shams, Dahnish <Shams.Dahnish@epa.gov>; Kapraun, Dustin <Kapraun.Dustin@epa.gov>
Cc: Cowen, Tracey [USA - EMP] <TCowen@versar.com>; Williams, Laura [USA - EMP] <lwilliams@versar.com>; Bogen, Kenneth [USA - EMP] <KBogen@versar.com>
Subject: RE: In-Vitro Update for Peer Review of PBPK Modeling for Chloroprene

Dahnish,
Draft report attached here. Let me know if you have any questions or need anything clarified. We will add in Dr. Smith's responses to this same report when we wrap that up

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From: Shams, Dahnish <Shams.Dahnish@epa.gov>
Sent: Tuesday, September 21, 2021 10:16 AM
To: Husain, Hassan [USA - EMP] <hhusain@versar.com>
Subject: RE: In-Vitro Update for Peer Review of PBPK Modeling for Chloroprene

OK great! Thanks Hassan. We do need his comments by late October to make sure we have the final report in hand before responding to the RFC.

- Dahnish

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From: Husain, Hassan [USA - EMP] <hhusain@versar.com>
Sent: Tuesday, September 21, 2021 10:10 AM
To: Shams, Dahnish <Shams.Dahnish@epa.gov>
Subject: RE: In-Vitro Update for Peer Review of PBPK Modeling for Chloroprene

Dahnish,
Will do, I can get that report into you today.
We'll also go ahead and get Dr. Smith initiated with the delivery date end of October.

Hassan Husain
Senior Program Manager

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From: Shams, Dahnish <Shams.Dahnish@epa.gov>
Sent: Tuesday, September 21, 2021 9:44 AM
To: Husain, Hassan [USA - EMP] <hhusain@versar.com>
Subject: RE: In-Vitro Update for Peer Review of PBPK Modeling for Chloroprene

Hi Hassan – Can we get the draft report without Dr. Smith's comments? We believe it might be too late for the RFC, but we would like his comments even if they come by late October.

- Dahnish

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From: Husain, Hassan [USA - EMP] <hhusain@versar.com>
Sent: Monday, September 20, 2021 4:36 PM
To: Shams, Dahnish <Shams.Dahnish@epa.gov>
Subject: RE: In-Vitro Update for Peer Review of PBPK Modeling for Chloroprene

Yes we have responses from everyone else
I'll keep a lookout for your response re: Dr. Smith

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From: Shams, Dahnish <Shams.Dahnish@epa.gov>
Sent: Monday, September 20, 2021 4:31 PM
To: Husain, Hassan [USA - EMP] <hhusain@versar.com>
Subject: RE: In-Vitro Update for Peer Review of PBPK Modeling for Chloroprene

Hi Hassan – See my responses in red below.

- Dahnish

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From: Husain, Hassan [USA - EMP] <hhusain@versar.com>
Sent: Monday, September 20, 2021 4:23 PM
To: Shams, Dahnish <Shams.Dahnish@epa.gov>
Subject: RE: In-Vitro Update for Peer Review of PBPK Modeling for Chloroprene

Dahnish,
Original comment deadline was September 7th. Did we get responses from everyone else?
Dr. Zhu submitted his comments on Friday. We are wrapping up the draft compilation report and can get that over.
In regards to the final reviewer:

Ex. 5 Deliberative Process (DP)

- Do you want us to send the compilation report with the current reviewer comments while we continue to look for the final reviewer? Yes please. A draft sometime this week would be great.
- Do you want to go forward with Dr. Smith/extend out the deadline? Let me check with Kris.

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From: Shams, Dahnish <Shams.Dahnish@epa.gov>
Sent: Monday, September 20, 2021 4:17 PM
To: Husain, Hassan [USA - EMP] <hhusain@versar.com>
Subject: RE: In-Vitro Update for Peer Review of PBPK Modeling for Chloroprene

Hassan – What was the deadline for comments to be received from the reviewers?

- Dahnish

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From: Husain, Hassan [USA - EMP] <hhusain@versar.com>
Sent: Wednesday, September 15, 2021 1:04 PM
To: Shams, Dahnish <Shams.Dahnish@epa.gov>; Kapraun, Dustin <Kapraun.Dustin@epa.gov>
Cc: Cowen, Tracey [USA - EMP] <TCowen@versar.com>; Williams, Laura [USA - EMP] <lwilliams@versar.com>; Bogen,

Kenneth [USA - EMP] <KBogen@versar.com>

Subject: RE: In-Vitro Update for Peer Review of PBPK Modeling for Chloroprene

Dahnish,

I can talk after 3:30, I'll send you a Teams invite

Hassan Husain

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From: Shams, Dahnish <Shams.Dahnish@epa.gov>

Sent: Wednesday, September 15, 2021 11:47 AM

To: Husain, Hassan [USA - EMP] <hhusain@versar.com>; Kapraun, Dustin <Kapraun.Dustin@epa.gov>

Cc: Cowen, Tracey [USA - EMP] <TCowen@versar.com>; Williams, Laura [USA - EMP] <lwilliams@versar.com>; Bogen, Kenneth [USA - EMP] <KBogen@versar.com>

Subject: RE: In-Vitro Update for Peer Review of PBPK Modeling for Chloroprene

Hi Hassan – Can you talk at 2:30 PM ET today or after 3:30 PM ET?

- Dahnish

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From: Husain, Hassan [USA - EMP] <hhusain@versar.com>

Sent: Tuesday, September 14, 2021 5:34 PM

To: Shams, Dahnish <Shams.Dahnish@epa.gov>; Kapraun, Dustin <Kapraun.Dustin@epa.gov>

Cc: Cowen, Tracey [USA - EMP] <TCowen@versar.com>; Williams, Laura [USA - EMP] <lwilliams@versar.com>; Bogen, Kenneth [USA - EMP] <KBogen@versar.com>

Subject: RE: In-Vitro Update for Peer Review of PBPK Modeling for Chloroprene

Dahnish,

Quick update on the candidates:

We continue to search for an in-vitro expert. To date we have contacted a total of 31 potential candidates for this expertise slot. At this point we are running into an issue of candidates with expertise are too closely related to the COI issues to be viable. I wanted to discuss with you further if you have some time Wednesday for a quick call.

On 9/3 we contacted the seven candidates listed below as well as sent a reminder earlier this week to those that hadn't replied yet:

Ex. 5 Deliberative Process (DP)

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Ex. 5 Deliberative Process (DP)

The five selected reviewers are:

Nan-Hung Hsieh, Ph.D.

California Department of Pesticide Regulation

Expertise: PBPK modeling; Statistics; Global sensitivity analysis; Metabolic rates *in vitro*

Kenneth M. Portier, Ph.D.

Independent Consultant

Expertise: Statistics; PBPK modeling; Global sensitivity analysis

Kan Shao, Ph.D.

Indiana University

Expertise: Statistics; Global sensitivity analysis

Raymond S. H. Yang, Ph.D.

Colorado State University

Expertise: PBPK modeling

Yiliang Zhu, Ph.D.

University of New Mexico School of Medicine

Expertise: Statistics; Global sensitivity analysis

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From: Shams, Dahnish <Shams.Dahnish@epa.gov>
Sent: Tuesday, September 14, 2021 10:25 AM
To: Husain, Hassan [USA - EMP] <hhusain@versar.com>; Kapraun, Dustin <Kapraun.Dustin@epa.gov>
Cc: Cowen, Tracey [USA - EMP] <TCowen@versar.com>; Williams, Laura [USA - EMP] <lwilliams@versar.com>; Bogen, Kenneth [USA - EMP] <KBogen@versar.com>
Subject: RE: In-Vitro Update for Peer Review of PBPK Modeling for Chloroprene

Hassan – All the candidates should likely be considered if available. Since we've been specifically trying to find someone with in vitro ADME experience, EPA would lean towards those with that type of lab experience. Knowledge of PBPK is a definite plus, but they all seem to have some of that.

Ex. 5 Deliberative Process (DP)

Let us know if you have any additional comments on this and if you make a selection from the candidates below.

- Dahnish

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From: Shams, Dahnish
Sent: Thursday, September 9, 2021 11:56 AM
To: Husain, Hassan [USA - EMP] <hhusain@versar.com>; Kapraun, Dustin <Kapraun.Dustin@epa.gov>
Cc: Cowen, Tracey [USA - EMP] <TCowen@versar.com>; Williams, Laura [USA - EMP] <lwilliams@versar.com>; Bogen, Kenneth [USA - EMP] <KBogen@versar.com>
Subject: RE: In-Vitro Update for Peer Review of PBPK Modeling for Chloroprene

Thanks Hassan! Let me huddle with the team.

- Dahnish

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O: (202) 564-2758

From: Husain, Hassan [USA - EMP] <hhusain@versar.com>

Sent: Thursday, September 9, 2021 11:05 AM

To: Shams, Dahnish <Shams.Dahnish@epa.gov>; Kapraun, Dustin <Kapraun.Dustin@epa.gov>

Cc: Cowen, Tracey [USA - EMP] <TCowen@versar.com>; Williams, Laura [USA - EMP] <lwilliams@versar.com>; Bogen, Kenneth [USA - EMP] <KBogen@versar.com>

Subject: RE: In-Vitro Update for Peer Review of PBPK Modeling for Chloroprene

Dahnish,
See below:

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Hassan Husain
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From: Shams, Dahnish <Shams.Dahnish@epa.gov>
Sent: Wednesday, September 8, 2021 12:02 PM
To: Husain, Hassan [USA - EMP] <hhusain@versar.com>; Kapraun, Dustin <Kapraun.Dustin@epa.gov>
Cc: Cowen, Tracey [USA - EMP] <TCowen@versar.com>; Williams, Laura [USA - EMP] <lwilliams@versar.com>; Bogen, Kenneth [USA - EMP] <KBogen@versar.com>
Subject: RE: In-Vitro Update for Peer Review of PBPK Modeling for Chloroprene

Hassan – Do you have any background information on the individuals below? Particularly, the pharma folks. Given that Yan and Ashton have declined, there is no need to provide information on them.

- Dahnish

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From: Husain, Hassan [USA - EMP] <hhusain@versar.com>
Sent: Tuesday, September 7, 2021 4:04 PM
To: Shams, Dahnish <Shams.Dahnish@epa.gov>; Kapraun, Dustin <Kapraun.Dustin@epa.gov>
Cc: Cowen, Tracey [USA - EMP] <TCowen@versar.com>; Williams, Laura [USA - EMP] <lwilliams@versar.com>; Bogen, Kenneth [USA - EMP] <KBogen@versar.com>
Subject: In-Vitro Update for Peer Review of PBPK Modeling for Chloroprene

Good afternoon Dahnish and Dustin,

I am writing to provide another update. We continue to search for an in-vitro expert. To date we have contacted a total of 31 potential candidates for this expertise slot. On Friday (9/3) we identified and contacted the seven additional candidates listed below:

Ex. 5 Deliberative Process (DP)

We just wanted to run the names by you to perhaps get some initial insight on names that may raise COI flags or other issues. So far two people have declined (Drs. Ashton and Yan). The remaining candidates have not responded yet. In addition, we recontacted Dr. Jordan Smith from the original panel to ask if he would reconsider participating due to the timeline extension. He requested additional information regarding the level of effort and the new deadline; however, he has not responded after receiving that information.

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

The five selected reviewers are:

Nan-Hung Hsieh, Ph.D.

California Department of Pesticide Regulation

Expertise: PBPK modeling; Statistics; Global sensitivity analysis; Metabolic rates *in vitro*

Kenneth M. Portier, Ph.D.

Independent Consultant

Expertise: Statistics; PBPK modeling; Global sensitivity analysis

Kan Shao, Ph.D.

Indiana University

Expertise: Statistics; Global sensitivity analysis

Raymond S. H. Yang, Ph.D.

Colorado State University

Expertise: PBPK modeling

Yiliang Zhu, Ph.D.

University of New Mexico School of Medicine

Expertise: Statistics; Global sensitivity analysis

As always let me know if you have any questions.

Hassan Husain

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